

Appl. No. 09/922,188  
Page 4  
Amdt. dated Dec. 13, 2003  
Reply to Office action of Sept. 17, 2003

Page 4

#### REMARKS/ARGUMENTS

Claims 1 – 9 and 11 remain in this application. Claim 43 is a new claim and is claim 10 rewritten in independent form. Claims 10 and 12 – 42 have been canceled.

#### Amendment of U.S. Patent Application 09/022/188

An Office action was received by applicant in late September 2003 which stated claims 1 – 9 of Group I were rejected because of 35 U.S.C. 103 [a] which forms the basis for all obviousness rejections set forth in this Office action cited patent application US 2003/0032857 A1 by Peter Forsell, which is titled, "Mechanical Anal Incontinence" dated Feb. 13, 2003, under Current U.S. Class. 600/30. Class 600/30 is for "Implanted" devices which specifies, "Subject matter wherein the incontinent device is surgically placed within the body to aid or replace a natural ringlike muscle, e.g., sphincter, normally maintains constriction of a body passage or orifice."

The Forsell patent application above is a continuation of his earlier U.S. Patent 6,464,628 B1 dated Oct. 15, 2002 by Peter Forsell. This '628 patent states in the "Summary of the Invention" on column 1, line 47; "Accordingly, the present invention provides an anal incontinence treatment apparatus, comprising: an adjustable restriction device implanted in a patient, who suffers from anal incontinence, and engaging a portion of the colon or rectum of the patient to restrict the fecal passage-way therein, and an adjustment device which mechanically adjusts the restriction device or release the fecal passageway."

In Column 2 in the paragraph beginning at line 3, the restriction device is described; "in the various embodiments hereinafter described the restriction device generally forms an at least substantially closed loop. However the restriction device may take a variety of different shapes, such as the shape of a square, rectangle or ellipse. The substantially closed loop could for example be totally flat, i.e. thin as seen in the radial direction. The shape of restriction device may also be changed during use, by rotation or movements of the restriction

device in any direction." In the continuation patent application US 2003/0032857 dated Feb. 13, 2003, it is again similarly stated under Summary Of The Invention in the second column on page 1, line 3 of paragraph [0009] "However, the restriction device may take a variety of different shapes, such as the shape of a square, rectangle or ellipse." The Office action stated on page 3, in item 4, beginning on line 6 says,"However, Forsell does not disclose the opening being elliptical. Forsell teaches a mechanical anal [page 4, line 1] incontinence device that can be shaped as a rectangular or ellipse. It would have been obvious to one having ordinary skill in the art at the time that the invention was made that the device as disclosed by Koch could be fabricated as a rectangular or an ellipse."

Applicant acknowledges that the surgically implanted "adjustable restriction device" could be in the shape of a square, rectangle or ellipse as patented on Oct. 15, 2002 and continued in patent application on Feb 13, 2003. The Forsell Mechanical Anal Incontinence device's function is to restrict the patient's colon inside the body, so fecal incontinence can be remedied. It is a rather complex invention that must be surgically implanted by competent medical doctors/surgeons. Applicant, however, can see no relationship or comparison between a simple, externally worn penile aid , to a surgically implanted device that clamps onto the colon or rectum inside the patient's body to control bowel or fecal control of a person afflicted with fecal incontinence. Applicant's invention merely causes the superficial dorsal veins located on top center of penis to be restricted. Applicant's simple device [shaped like a horizontal ellipse] has nothing what ever to do with fecal incontinence. Rather, it provides a simple, yet functional device that fits compactly at the base of the male organ and can be applied or removed in less than 3 seconds. It is a compact "externally worn" anatomical device. Many dozens of male sexual aids have been filed under U.S. Class. 600/38. Applicant asked Esq. James Duncan why application was filed under Class 128/883 instead of 600/38? He said Patent Office assigned this classification to applicant's application for the anatomical device.

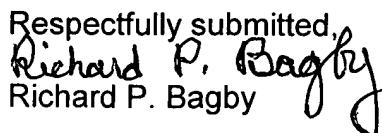
Applicant is not aware of any other horizontally elliptical penile aids. Unlike the Forsell surgically implanted "Mechanical Anal Incontinence" device, applicant's anatomical device was invented with the objective of enhancing the male's penile anatomy for his greater sexual performance and pleasure.

Applicant's invention operates on a different principle than many of the "round ring" designs that merely constrict and reduce venial flow of blood in the portions of the penis periphery engaged thereby. Although applicant's elliptical invention may have the same interior circumference as a round or split ring device, the

approximately 50 degree elliptical shape results in a shape whose vertical diameter is about 17% less than the round ring and about 17% wider, horizontally. Horizontal ellipses by their very configuration are shorter in their vertical diameter. Since the male penis is more "elliptical" in shape, than round, the elliptical shape achieves the desired result of fitting more naturally as it accommodates the natural elliptical shape of the penis. Its shorter vertical dimension ensures more localized pressure will be applied to the superficial dorsal veins. Applicant's invention is fabricated of materials of sufficient strength so its unique elliptical shape will not deform and thus be compromised. This ensures that the two sides that support or cradle the underside of the penis will maintain their modest angle of about 25-35 degrees. This achieves a sufficient upward force to lift the organ firmly against the top of the ellipse to effectively restrict the superficial dorsal veins, which are located at the top center of the base of the penis. These dorsal veins are the principle return veins for the penis. This wider area of support the elliptical shape provides by the wider cradle, allows for more clearance around the urethra without sacrificing the needed "lift" as it pushes the organ firmly upwards. There is sufficient clearance between the distal ends that device need never touch the bottom of the urethra and thus constrict it. The "anatomically correct" elliptical shape so configures to the penis' natural shape thus the device "rotating" or "twisting" is prevented. This ensures that the necessary clearance around the urethra is constantly maintained. In all drawings applicant has seen in medical books that illustrate human anatomy, the cross sectional drawings of the penis [such as illustrated by Web MD. on line] show the penis to be more elliptical in shape [especially when in erect state] rather than circular or round. Applicant's 1974 patent 3794020 employs a drawing from a medical book that illustrates this well. Invention's elliptical configuration uses to advantage the natural horizontally elliptical shape of organ, to maximize support of underside of organ while still ensuring the comfort of the man wearing it. In this application a penile aid that is shorter in vertical diameter, but wider in horizontal diameter accomplishes the optimum goal of more localized pressure on the dorsal veins, without compromising user's comfort or safety. Applicant has restricted application to the Elliptical embodiments as described in claims 1 – 9 and 11 and 43.

Applicant believes that claims 43 and 11 are in an allowable condition and the foregoing remarks place claims 1 – 9 in an allowable condition.

Applicant respectfully request that a timely Notice of Allowance be issued in this case.

Respectfully submitted,  
  
Richard P. Bagby